



AMERICAN ACADEMY OF
HOSPICE AND PALLIATIVE MEDICINE

April 1, 2019

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Office of the Assistant Secretary of Health
200 Independence Avenue, SW
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Submitted electronically via www.regulations.gov

RE: HHS–OS–2018–0027; Request for Public Comments on the Pain Management Best Practices Inter-Agency Task Force Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations

Dear Dr. Singh:

On behalf of the more than 5,200 members of the American Academy of Hospice and Palliative Medicine (AAHPM), thank you for the opportunity to provide input on the Pain Management Best Practices Inter-Agency Task Force Draft Report. The Academy commends the Task Force for its careful review of the many critical issues highlighted in the report, its patient-centered approach in evaluating best practices, and its emphasis on ensuring there is sound evidence to support its recommendations.

AAHPM is the professional organization for physicians specializing in Hospice and Palliative Medicine. Our membership also includes nurses, social workers, spiritual care providers, and other health professionals deeply committed to improving quality of life for patients facing serious illness, as well as their families and caregivers. The timely and effective management of pain and other distressing symptoms is central to providing these patients with high-quality palliative care, and opioid analgesics are a critical tool in alleviating that suffering.

AAHPM appreciates that the Task Force's analysis of best practices for pain management occurs in the context of a national crisis characterized by rising rates of opioid use disorder and overdose death, and we believe that many of the recommendations put forth in the Draft Report, if implemented, will go a long way toward ensuring patients with pain receive high-quality care, including treatment with opioids when they are medically indicated and can be taken safely.

Our Academy has been particularly concerned with how best to balance the growing challenges related to managing pain with opioids with the need for ready access to appropriate pain medications for patients with serious or complex chronic illness and those at the end of life — patients for whom high-dose opioids may be necessary and medically appropriate. The Academy recognizes there is an indisputable public health imperative to curb opioid use disorder, misuse, and diversion, and is deeply committed to both providing continuing education that results in optimal pain management and optimal care for all patients and to collaborating with professional, regulatory and industry stakeholders to maximize individual and public safety.

At the same time, AAHPM believes public and payer policies must recognize there is an equally important public health imperative to ensure that our sickest, most vulnerable patients have access to timely, effective treatment of their pain and suffering. We have serious and growing concerns regarding policies that aim to limit opioid production, availability, and/or dosage and duration of prescriptions and would impede the individualization of treatment to patient needs. These efforts serve to paint all pain and all patients as the same and threaten access to appropriate care for patients with serious illness. We therefore strongly support the Task Force in emphasizing that a “one size fits all” approach is never appropriate.

Patients with pain are not all the same, so managing pain effectively and safely requires an individualized approach based on many factors, including pain syndrome, patient risk factors, underlying illnesses, life expectancy, clinical expertise, degree of control and monitoring available to the treatment team, and appropriate goals of treatment (for many patients not just relief of pain, but also optimal physical and mental function, preserved work and family role, quality of life and survival). Especially when taking care of individuals with serious and life-limiting illness, we must be able to carefully titrate interventions to the circumstances unique to that patient. The primary goal should be ensuring a patient’s pain and other distressing symptoms are adequately controlled.

Increasingly, however, we have seen how well-intentioned public policy can impose undue burdens on legitimate prescribers and sow confusion, creating a cooling effect under which physicians are unwilling to prescribe opioids in even the most clearly legitimate circumstances. Moreover, regulations requiring referral of patients on chronic opioids to a pain specialist place an undue strain on pain management physicians, and we know there are simply not enough specialists (including palliative medicine specialists) to meet such requirements. As a result, patients with serious illness and profound pain issues can wait for days to weeks for medications while primary care physicians seek a consulting specialist, even when only minor medication adjustments are needed. With an increasing number of prescribers, especially primary care providers, hesitant to prescribe opioids at all, even when clinically indicated, our members have reported receiving referrals of chronic pain patients to the hospice setting even when they are not really hospice eligible, in order to “hand off” these patients.

AAHPM appreciates the Task Force’s attention to these multiple challenges. Our Academy’s feedback on some of the Draft Report’s specific recommendations follows below.

Clinical Best Practices

Approaches to Pain Management — AAHPM offers strong support for the Task Force approach that recognizes the value of and seeks to encourage coordinated and collaborative care. AAHPM further appreciates that the Task Force has emphasized the importance of a multimodal and multidisciplinary approach to pain management. In two convenings of the Integrative Pain Care Policy Congress, our Academy joined dozens of organizations representing healthcare providers, public and private payers, policy experts, and pain research and patient advocacy organizations to consider joint strategies for advancing individualized care for people with pain. Participants developed and worked from the following consensus definition:

Comprehensive integrative pain management (CIPM) includes biomedical, psychosocial, complementary health, and spiritual care. It is person-centered and focuses on maximizing function and wellness. Care plans are developed through a shared decision-making model that reflects the available evidence regarding optimal clinical practice and the person’s goals and values.

We encourage the Task Force to review the Draft Report’s use of terms (such as “integrated,” “integrative,” “multimodal,” “holistic,” and “comprehensive”) that, in places, seem to be used interchangeably and to consider where it may be helpful to substitute CIPM (per the consensus definition) or otherwise define terms if they are intended to mean different things.

Medication — AAHPM supports the recommendation for timely consultation with pain and other specialists, and we’d urge the Task Force to specifically highlight the importance of palliative care consultations in this context. At

the same time, while we also agree that medication guidelines for specific populations and condition-specific algorithms can be useful, care must be taken not to separate populations in a way that complicates treatment (separating cancer/non-cancer pain) or reimbursement (per Recommendation 2e), or otherwise precludes providers from ultimately deferring to their professional judgment based on a patient's individual needs. AAHPM thus strongly supports Task Force Recommendation 2c: "The type, dose, and duration of opioid therapy should be determined by treating clinicians according to the individual patient's need and pain condition." As such, we urge the Task Force to amend its recommendations suggesting "non-opioids should be used as first-line therapy whenever possible in the in-patient and out-patient settings" to more clearly state that this must only be the case "when clinically appropriate."

Prescription Drug Monitoring Programs (PDMPs) — AAHPM supports the use of PDMPs as a clinical tool and appreciates that the Draft Report recommends that prescribers determine when it makes sense to use program data, so as to avoid unnecessary burden to the provider team. To ensure the value of PDMPs, and in alignment with our Academy's own guidelines for effective PDMPs, we support the call for EHR integration and interoperability that would allow for providers to access data across states and within and outside of federal health care entities. However, given that evidence is lacking to support when PDMP data is best used and there exist limitations on accessibility of such data, we would suggest the Task Force add a caution regarding quality measurement tied to PDMP queries (soon to be required under MIPS and the Hospital Promoting Interoperability program). Finally, as Hospice and Palliative Medicine specialists typically work to support a patient's other healthcare providers, we very much appreciate that the Task Force has flagged the importance of pharmacists understanding that doctors often work as teams, so that "doctor shopping" is a conclusion made after a pharmacist has made contact with the provider. (Many of the above concerns are highlighted in this [discussion](#) of a Quality Improvement project examining PDMP queries at a cancer center's palliative care clinic.)

Screening and Monitoring — While AAHPM supports the general scope of the recommendations in this section, we appreciate that the Draft Report addresses both the value of and the lack of evidence for some screening tools. We therefore urge an additional recommendation that the use of such screening tools should be determined by the physician in light of the individualized patient circumstances and characteristics. For example, mandating patient treatment agreements would be inappropriate for hospice patients with a prognosis of days or weeks, so any statutes or institutional policies intended to apply universally should include appropriate exemptions for patients in hospice with no identified risk factors for opioid abuse or diversion. In addition, as a growing number of states legalize recreational marijuana, we would point to the need to include as a gap the lack of research and guidance for clinicians that encounter a positive THC on a urine screen in a state where marijuana is legal.

Overdose Prevention and Education — AAHPM endorses efforts to expand availability of naloxone, but would urge an amendment to Recommendation 1a regarding naloxone co-prescribing/dispensing to ensure carve-outs for patients at the end of life, noting that co-prescribing and dispensing must be clinically appropriate. The reference to patient/family education should also be expanded to include provider education on whether/when naloxone is appropriate. For example, we have heard from a member who has seen naloxone given to a dying cancer patient on high-dose opioids because a well-meaning EMT misinterpreted the decline associated with dying as being opioid overdose. This resulted in ICU admission for a hospice patient who went into complete opioid withdrawal while simultaneously unmasking all their opioid-managed pain.

Interventional Procedures, Behavioral Health Approaches, and Complementary and Integrative Health — AAHPM applauds the attention to nonpharmacological approaches to pain management addressed in this Draft Report. As part of a multidisciplinary approach to pain, we echo the need for reimbursement mechanisms for these interventions, including consistent and timely insurance coverage for evidence-informed interventional procedures early in the course of treatment when clinically appropriate, for psychological and behavioral health interventions (including through alternative treatment delivery, such as telehealth), and for complementary and integrative therapies that have been shown to be effective for pain management. These treatments must be covered by Medicare, Medicaid and private payers if they are to become mainstream and accessible. Otherwise prescribers will necessarily default to treatments, like opioids, that are reimbursed in order to ensure their patients' pain is managed.

Special Populations — AAHPM commends the Task Force for highlighting health disparities across racial and ethnic populations as well as those facing patients with conditions such as sickle cell disease. We applaud the attention given to the unique needs of special populations, including both pediatric and geriatric patients, where pain management education and guidelines are lacking. However, we'd urge the Task Force to amend its recommendations to include patients with a limited prognosis, as often encountered in hospice and palliative care, and patients who are cognitively impaired. Both of these patient populations have chronic medical problems and are likely to receive treatment with opioids, and they are frequently managed by practitioners who do not specialize in pain or palliative care. Moreover, individuals with opioid use disorder also may suffer with a serious or terminal illness and require opioid treatment. AAHPM would be deeply concerned if policies sought to preclude prescribing opioids to these patients or restrict coverage or reimbursement for appropriate opioid use for individuals suffering from OUD. Not providing appropriate pain management for a patient suffering from OUD who is seriously ill would have dire consequences, including the patient potentially seeking relief in illicitly obtained opioids and other narcotics.

Cross-Cutting Clinical and Policy Best Practices

Stigma, Education, Access, and Coverage — AAHPM shares the Task Force's concerns about the impact of stigma on patients' access to timely, appropriate pain treatment and the need to improve provider and patient education. AAHPM has been a leader in prescriber education and safe use of opioids. At the same time, we urge the Task Force to ensure that prescriber education is properly targeted and incentivized, so practitioners actually learn when opioids are appropriate along with best practices for prescribing them, rather than opt out of doing so altogether.

With regard to ensuring access to needed medication, AAHPM supports the Task Force's focus on medication shortages. Our members have reported that limits on opioid production and other shortage issues have compromised patient care in our field. Renewed attention to the various factors contributing to these often unanticipated crises is essential to ensuring patients receive appropriate care when they are most vulnerable.

Finally, AAHPM supports the Draft Report recommendation that CMS and other payers compensate according to physician-patient time spent in education of patients/families, echoes the need for improved reimbursement policies that better account for the time and resources required to provide appropriate screening and treatment, and agrees that CMS and private payers should investigate and implement innovative payment models that recognize and reimburse comprehensive, integrative pain management therapies.

Workforce — The Draft Report notes there is a lack of multidisciplinary physicians and other health care providers who specialize in pain. AAHPM would suggest that palliative medicine be added to list of specialties recognized as having particular expertise in pain and symptom management and that relevant recommendations regarding expanded support for education and training of physicians and nonphysician specialists include palliative care.

Research — AAHPM agrees with the Task Force that we must develop a better understanding of the mechanisms of pain and appreciates that the Draft Report recognizes the acute need for more research on safe and effective treatments for pain, which our Academy has pointed to through a provision in the Palliative Care and Hospice Education and Training Act. We therefore strongly support the Task Force recommendation for increased funding for pain research. Congressional support will be essential to meet these funding goals and to direct relevant agencies to better coordinate ongoing research efforts. In addition, we'd suggest the Task Force recommend that the Food and Drug Administration prioritize and accelerate approval of adjuvant analgesics to decrease the need for opioids as well as recommend that policymakers ease current barriers to medical research on cannabinoids.

Review of the CDC Guideline

AAHPM greatly appreciates the Task Force's considered examination of the CDC Guideline for Prescribing Opioids for Chronic Pain and the impact its misapplication has had on patients and prescribers. The November 2018 statement from the American Medical Association advocating against such misapplication cited in the Draft Report

resulted directly from efforts by AAHPM and its specialty society partners in the AMA Pain and Palliative Medicine Section Council, whose members increasingly report concerns regarding professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the morphine milligram equivalent (MME) thresholds included in the CDC Guideline.

To date, there is no scientific basis to support calls to restrict the dosage and duration of opioid treatment for pain, and AAHPM objects to such considerations as they would unduly burden patients with serious and life-threatening illness. As a population, these patients typically need higher doses of opioids, often for long periods. With this in mind, AAHPM would urge the Task Force to note that any revision to the CDC Guideline must not be based on the assumption that “high prescribing” equals “bad prescribing.” For some specialties, high prescribing patterns may be the norm and completely appropriate. For other specialties, even low prescribing may be inappropriate and not indicated.

AAHPM would oppose any recommendation that would preclude an individualized approach to palliative care patients’ legitimate needs. Dosing and duration limits for opioids would cause unnecessary suffering for hundreds of thousands of patients and paradoxically sacrifice patients’ safety by leaving them in terrible pain each day that they live past an arbitrary cutoff of their medication. It would be ideal if CDC recommendations were one of a number of rational considerations that prescribers use to guide treatment, along with evidence for best practices and an individual’s unique circumstances and goals of care. Instead, we have seen it is more likely that any suggested restrictions are inappropriately adopted as rules and codified in statute. Moreover, while the CDC’s recommendations are meant to apply to primary care outside of cancer, palliative and end-of-life care, health systems, pharmacy benefit managers and payers are in fact using the CDC Guideline to impose limits on opioid prescriptions regardless of a patient’s diagnosis or goals.

Thank you again to the Task Force for its comprehensive examination of best practices for pain management and the current barriers to achieving optimal, patient-centered care for patients with pain. Setting aside its financial costs, unrelieved pain causes inordinate human suffering resulting in longer hospital stays, increased readmissions and outpatient visits, and decreased ability to function or enjoy quality of life. AAHPM greatly appreciates the opportunity to provide feedback on the Draft Report, which recognizes both the public health imperative to ensure patients receive timely, appropriate treatment for their pain and suffering and the pressing need to maximize individual and public safety in the face of unacceptable rates of opioid use disorder and overdose death. AAHPM stands ready to serve as partner in achieving the balance necessary to ensure both aims are met. As you review our specific comments, please know that we would welcome any further opportunities to provide stakeholder feedback or connect you with our physician leadership as the work of the Task Force progresses. Please address questions to Jacqueline M. Kocinski, MPP, AAHPM Director of Health Policy and Government Relations, at jkocinski@aahpm.org or 847-375-4841.

Sincerely,



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